THE CENTER...

The Minneapolis Center for Chronic Disease Outcomes Research (CCDOR) was established in April 1998. Its mission is to enhance, through research, education and dissemination activities, the delivery and accessibility of high-quality, cost-effective health care that will result in optimal clinical, psychosocial, and functional outcomes for veterans with chronic disease. The Center has grown into a vibrant, productive organization supporting 70 funded projects with an annual budget of over $12 million. The Center's leadership includes Dr. Hanna E. Bloomfield (formerly Rubins) (Director), Dr. Melissa Partin (Associate Director), Dr. Kristin L. Nichol (Senior Research Scientist), and a distinguished steering committee, chaired by Dr. Richard Lofgren.

Department of Veterans Affairs

CORE RESEARCH STAFF

Core Investigators
Hanna E. Bloomfield MD, MPH (Director)
Melissa Partin, PhD (Associate Director)
Kristin Nichol, MD, MPH, MBA (Senior Research Scientist)
Diana Burgess, PhD
Kristine Ensrud, MD, MPH
Howard Fink, MD, MPH
Steven Fu, MD, MSCE
Joan Griffin, PhD
Hildi Hagedorn, PhD
Yvonne Jonk, PhD
Anne Joseph, MD, MPH
Laura Kochevar, PhD
Frank Lederle, MD
Maureen Murdoch, MD, MPH
David Nelson, PhD
Siamak Noorbaloochi, PhD
Thomas S. Rector, PharmD, PhD
Nina Sayer, PhD, LP
Michele Spoont, PhD
Michelle van Ryn, PhD, MPH

Core Investigators (cont.)
Erin Warshaw, MD, MS
Timothy Wilt, MD, MPH

Postdoctoral Fellows
Greta Friedemann-Sánchez, PhD
Brent Taylor, PhD

Core Statistics and Data Group
Sue Aumer, MS
Ann Bangerter, BS
Barbara Clothier, MS
Larry Fortier, MA
Joseph Grill, MS
Sean Nugent, BA
Tamara Schult, MPH
Diane Smith, BA
Joanne Thomas, BS

Administrative Staff
Mike Abel, BA
Michele Haas, BA
Jill Johnson, BA
Suzanne Leger, MPA
Rod Mac Donald, MS
Indy Rutks, BS
Joe Sabol, MBA

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Please direct comments or suggestions to the Editor: Michele Haas • Tel 612.467.1685 • Fax 612.727.5699
www.hsrd.minneapolis.med.va.gov

ccdor CENTER FOR CHRONIC DISEASE OUTCOMES RESEARCH
VA MEDICAL CENTER 152/2E . ONE VETERANS DRIVE . MINNEAPOLIS, MN 55417

ccdor CENTER FOR CHRONIC DISEASE OUTCOMES RESEARCH connections

VOL 7 • ISSUE I • SPRING 2005

FEATURED RESEARCH

EFFECTIVENESS OF STATIN THERAPY IN ADULTS WITH CORONARY HEART DISEASE

Timothy J. Wilt, MD, MPH; Hanna E. Bloomfield, MD, MPH; Roderick Mac Donald, MS; David Nelson, PhD; Indulis Rutks, BS; Michael Ho, MD; Gregory Larsen, MD; Anthony McCall, MD, PhD; Sandra Pineros, MPH; Anne Sales, PhD

Background. We conducted a meta-analysis of patients with coronary heart disease (CHD) to determine the effectiveness of statin therapy; whether effectiveness varied according to patient characteristics, outcomes, or pretreatment low-density lipoprotein cholesterol (LDL-C) levels; and the optimal LDL-C goal and the level at which to initiate statin therapy.

Methods. Randomized trials or systematic reviews for secondary prevention of CHD with statin therapy published between January 1966 and December 2002 were identified through MEDLINE and the Cochrane Library. Studies were included if they randomly assigned adults with CHD to statin therapy or control, enrolled at least 100 individuals per arm, reported clinical outcomes and LDL-C levels, and were published as full studies in English. Two reviewers abstracted data using a prospectively designed protocol.

Results. Twenty-five studies enrolling 69,511 individuals were included. Participants in 19 placebo-controlled trials had a mean age of 63 years and a mean pretreatment LDL-C level of 149 mg/dL (3.85 mmol/L); 23% were women. Statin therapy reduced CHD mortality or nonfatal myocardial infarction 25% (relative risk [RR], 0.75; 95% confidence interval [CI], 0.71-0.79), all-cause mortality 16% (RR, 0.84; 95% CI, 0.79-0.89), and CHD mortality 23% (RR, 0.77; 95% CI, 0.71-0.83). Beneficial effects were seen in women and the elderly. There were no data to determine whether lowering the LDL-C level to less than 100 mg/dL (<2.59 mmol/L) was superior to lowering it to 100 to 130 mg/dL (2.59-3.36 mmol/L). Meta-regression analyses revealed risk reductions for CHD mortality or nonfatal myocardial infarction and major vascular events across available pretreatment LDL-C levels.

Conclusion. Statin therapy reduces mortality and morbidity in adults with CHD, even at pretreatment LDL-C levels as low as 100 mg/dL (2.59 mmol/L).

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TELESTOP STUDY RESULTS

The objective of TELESTOP, a randomized controlled trial funded by VA HSR&D, was to determine if telephone care increases the rate of smoking cessation compared to typical treatment initiated in Primary Care. Smoking cessation interventions tend to be referral based, multi-session and often occur in a group setting. Often only one type of treatment is available at any given center/facility; thus, patients have limited options if initial treatment is not effective. Telephone care has been found to be an effective strategy to increase access to tobacco cessation treatments. It is individual, easily tailored to a person's needs and accessible, which is an important consideration when working with an older, sicker population. However, the question of whether telephone care would prove effective in a veteran population had not been studied prior to TELESTOP.

TELESTOP Study Continued on page 7

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calendar

VA HSR&D Service Annual Meeting
February 16-18, 2005
Baltimore, MD

9th Annual MN Health Services Research Conference
March 1, 2005
Four Points by Sheraton
Minneapolis, MN

CCDOR Research Seminar
Joan M. Ostrove, PhD
Macalester College
Dept of Psychology
March 17, 2005
Minneapolis VAMC
3:30 PM

FEATURED RESEARCH

Continued from page 1

RANDOMIZED TRIAL EXAMINING THE EFFECT OF TWO PROSTATE CANCER SCREENING EDUCATIONAL INTERVENTIONS ON PATIENT KNOWLEDGE, PREFERENCES, AND BEHAVIORS

Melissa R. Partin, PhD; David Nelson, PhD; David Radosevich, PhD; Sean Nugent, BA; Ann B. Flood, PhD; Nancy Dillon, RN, PhD; Jeremy Holtzman, MD, MS; Michele Haas, BA; Timothy J. Wilt, MD, MPH

Objective: To assess the effect of video and pamphlet interventions on patient prostate cancer (CaP) screening knowledge, decision-making participation, preferences, and behaviors.

Design: Randomized, controlled trial.

Patients/Participants: One thousand, one hundred fifty-two male veterans age 50 and older with primary care appointments at participating facilities were randomized and 893 completed follow-up.

Interventions: Patients were randomized to mailed pamphlet, mailed video, or usual care/control.

Measurements and Main Results: Outcomes assessed by phone survey 2 weeks postintervention included a 10-item knowledge index; correct responses to questions on CaP natural history, treatment efficacy, the prostate-specific antigen (PSA)'s predictive value, and expert disagreement about the PSA; whether screening was discussed with provider; screening preferences; and PSA testing rates.

Mean knowledge index scores were higher for video (7.44; P=.001) and pamphlet (7.26; P=.03) subjects versus controls (6.90). Video and pamphlet subjects reported significantly higher percentages of correct responses relative to controls to questions on CaP natural history (63%, 63%, and 54%, respectively); treatment efficacy (19%, 20%, and 5%), and expert disagreement (28%, 19%, and 8%), but not PSA accuracy (28%, 22% and 22%). Pamphlet subjects were more likely than controls to discuss screening with their provider (41% vs 32%; P=.03) but video subjects were not (35%; P =.33). Video and pamphlet subjects were less likely to intend to have a PSA, relative to controls (63%, 65%, and 74%, respectively). PSA testing rates did not differ significantly across groups.

Conclusions: Mailed interventions enhance patient knowledge and self-reported participation in decision making, and alter screening preferences. The pamphlet and video interventions evaluated are comparable in effectiveness. The lower-cost pamphlet approach is an attractive option for clinics with limited resources.

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EFFECTIVENESS OF LIPID-LOWERING MEDICATIONS IN OUTPATIENTS WITH CORONARY HEART DISEASE IN THE DEPARTMENT OF VETERANS AFFAIRS SYSTEM*

Hanna Bloomfield Rubins, MD, MPH; David B. Nelson, PhD; Siamak Noorbaloochi, PhD; Sean Nugent, BA

Lipid therapy aimed at reducing low-density lipoprotein cholesterol has been shown, in several large-scale randomized controlled trials, to reduce coronary heart disease (CHD) morbidity and mortality and all-cause mortality in patients with established CHD. However, lipid therapy's effectiveness in usual clinical settings has not been extensively studied. The purpose of this study was to determine the effect of prescription lipid-lowering medication (LLM) on all-cause mortality in a cohort of patients with known CHD. We conducted a retrospective cohort study using linked administrative and clinical databases. Sixteen thousand four hundred seventy patients with CHD who were outpatients at 1 of 5 Veterans Affairs medical facilities in the upper midwest between 1994 and 1996 were identified and then followed until death or the end of the study (December 31, 2000). Pharmacy databases were used to determine whether patients had been prescribed LLMs. Demographics, comorbid conditions, cardiac medications, and lipid levels were collected. Time-dependent Cox proportional hazards analyses, adjusted for confounding variables, and the propensity score for LLM use were performed to compare survival between those prescribed and those not prescribed LLM. During an average follow-up of 5.9 years, there were 4,821 recorded deaths in patients not prescribed LLM (51%) and 1,245 deaths in patients prescribed LLM (18%). On average, the treated cohort survived 15 months longer than the untreated group (p<0.0001). The age-adjusted hazards ratio associated with LLM use was 0.59 (95% confidence interval 0.55 to 0.63, p=0.0001). After adjusting for propensity score, age, and previous use of LLM, the hazard ratio associated with prescription of LLM was 0.77 (95% confidence interval 0.70 to 0.85, p<0.0001). This study confirms, in a standard clinical setting, the beneficial effects of LLM on total mortality in patients with established CHD. These data suggest that the benefits of lipid therapy observed in highly controlled randomized trials are attainable in usual clinical settings.

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FEATURED RESEARCH

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Subjects were recruited from five former VISN 13 VA Medical Centers (Minneapolis, St. Cloud, Fargo, Black Hills, Sioux Falls), now part of the VISN 23 VA Midwest Health Care Network, between June 2001 and December 2002. Since smoking status was not available in CPRS, a general invitation letter was mailed to 68,903 veterans who had been seen in a primary care clinic at a participating medical center within the year prior to initiation of the study. Of these veterans, 1831 responded to the letter and 995 met the protocol's eligibility criteria. A total of 838 smokers were randomized; 420 were included in the standard care group and 418 in the telephone care group. The standard care group received routine health care provided by the medical center while the telephone care group received behavioral counseling (delivered by 7 call relapse-sensitive protocol) over a two-month period as well as smoking cessation medications (nicotine patch, nicotine gum, bupropion SR) as clinically indicated, provided by the call center.

Study outcomes were abstinence from smoking at 3 and 12-month follow-up, duration of abstinence and number of quit attempts. At the 12 month follow-up, 13% of individuals in the telephone treatment group had abstained from smoking for six months or more, compared to 4.1% in the control group (Odds Ratio = 3.50, 95% Confidence Interval 1.99-6.15, p<0.001). All outcomes showed statistically significant improvement in the telephone treatment group compared to usual care, including 7 day point prevalent abstinence (39.6% vs. 10.1%, p<0.001). The study found that smokers who received telephone counseling were also more likely to utilize smoking cessation medication and made more attempts to quit smoking.

According to the study's principal investigator, Anne Joseph, MD, MPH, comprehensive telephone care with behavioral therapy should be made available to all veterans. While there are non-VA national quit lines available through the National Cancer Institute and the National Cancer Society, veterans may be less likely to use these lines because it is difficult to coordinate with medications. It would be ideal to create a VA National Quit Line (utilizing an 800 number) that would blend seamlessly with the veterans' current medical care.

Anne Joseph, MD, MPH

A positive outcome of this study was the collaboration it fostered with international quit line expert Shu-Hong Zhu, PhD, who helped design a model of behavioral counseling and adapt it to the VA system. In 2004, Dr. Joseph was awarded (unsolicited) funds from the Public Health Strategic Health Care Group (PHSHG) to study further implementation of the model within the VA. This tobacco cessation demonstration project focuses on different methods to recruit smokers to telephone care, such as contacting smokers while they are hospital inpatients.

QUERI CORNER (CONT.)

The QUERI has also strengthened its relationships with vital management and policy partners this year:

- We assisted the VA GI Field Advisory Group with a survey of GI specialists' opinions.
- We assisted the National Chief Medical Officers with a survey of national CRC screening and diagnostic practices
- We presented a summary of our activities to the National Leadership Board

Next month, we will be presenting a plan for monitoring CRC screening, diagnosis and treatment to the Office of Quality and Performance and Patient Care Services.

Michelle vanRyn, who as Research Coordinator led the QUERI through its vital formative stages, has moved her base of operations to the University of Minnesota. Although the QUERI will still benefit from Michelle's participation in several active research projects, we will miss the day-to-day input from her.

Laura Kochevar, former QUERI Implementation Research Coordinator, has taken up the Research Coordinator Role and is enjoying the support of the executive committee and CCDOR colleagues in moving the QUERI forward. This will be aided by the addition of Suzanne Leger as QUERI Administrative Officer. Nancy Koets is continuing in her role as implementation research associate.

Together, the local and national QUERI partners look forward to making FY 05 equally successful.

INTRODUCTIONS

DIANA BURGESS, PHD

Originally from New York, Diana earned a BA in Art & Art History at Rice University in Houston. Her interest in social justice issues led her to the University of Minnesota, where she received a PhD in social psychology in 1998. As a doctoral student, she drew upon social-psychological theories of stereotyping to pursue research that explained different ways by which stereotypes contribute to gender discrimination. As a post-doctoral fellow in organizational behavior at Stanford University Graduate School of Business, Diana continued her research in stereotyping and became interested in understanding how people function in the context of organizations.

It was her interest in organizational behavior theory that led Diana to take a position with General Mills, where she worked from 1999 to 2002. Her work included ethnographic research on consumers and understanding barriers to the flow of knowledge between organizational divisions. It was her experiences at General Mills that reinforced her desire to conduct applied research that could best be accomplished in the world of academia. Thus, she became involved with the DREGAN project, a partnership with community organizations and the Minnesota Partnership for Action Against Tobacco (MPAAT), aimed at reducing tobacco use in the Latino and Asian communities. It was her work with the DREGAN project that led to a post-doctoral fellowship at CCDOR in August 2003 and culminated in her joining the Center as an investigator one year later.

At CCDOR, Diana has the opportunity to apply her prior training and research in organizational and social psychology to the health care arena, focusing on reducing social inequality across organizational groups, gender and racial lines. Expanding upon her collaborative relationships with other investigators within the Center, Diana recently submitted a VA HSR&D MREP Mentoring and Career Plan, with the overall goal of understanding and ameliorating healthcare disparities, with special focus on the documented disparities in pain management.

On a personal note, Diana and her husband Mark reside in Minneapolis with their 3 year old twin sons. Diana enjoys cooking, hosting dinner parties, participating in her book club and writing group, and walking around the local lakes with her family.

THOMAS RECTOR, PHARMD, PHD

Tom originally hails from WI and completed a BS in Pharmacy at the University of WI at Madison. He quickly went on to complete a PharmD at the University of MN, where he performed pharmacokinetic research at the U of MN College of Pharmacy for two years. Through a grant from the Kellogg Foundation established to train clinical pharmaceutical scholars, Tom returned to graduate school at the U of M and earned a PhD in Pharmacy.

While his initial interests focused on laboratory research, the Kellogg grant opened up new opportunities, leading Tom toward clinical research, pharmacoepidemiology and biostatistics. From 1983 to 1996, he worked at the Cardiovascular Division of the U of M Medical School, investigating treatments and prognoses of patients with heart failure and mentoring cardiology fellows. He developed the Minnesota Living with Heart Failure questionnaire, a widely used measure of the effects of heart failure on patients' quality of life. In 1997, Tom joined the Center for Health Care Policy and Evaluation at the UnitedHealth Group as a health services researcher.

With his multi-faceted research background, Tom was a good fit for CCDOR and he joined the Center as an investigator in 2004. He appreciates the opportunity to further his efforts in heart failure research and has recently contributed to a proposal for a new QUERI Center focusing on heart failure. In addition to his role as an investigator, Tom serves as a research mentor and consultant for the Minneapolis VA Center for Epidemiological and Clinical Research (CECR).

On a personal note, Tom is an avid golfer and presents strong evidence that the golf season in Minnesota is not as short as one might reasonably expect. He and his wife Mary live in Vadnais Heights; their son Scott will soon graduate from Mankato State.

NEW CENTER CREATES OPPORTUNITY AT MINNEAPOLIS VAMC

The recently established Center for Epidemiological and Clinical Research (CECR), located within CCDOR at the Minneapolis VA, offers junior faculty a valuable training opportunity in clinical research. The objectives of the program are to develop new independent investigators who perform exemplary clinical research related to veterans' health issues and to foster clinical research at the Minneapolis VAMC.

Five faculty members from diverse clinical disciplines are matched to a Content Mentor within their area of expertise and a Core Mentor, a clinical researcher from CCDOR. According to program director Dr. Frank Lederle, "the program had an auspicious start when each of the five participants were paired with their first choice for mentor." Core Mentors are full-time VA general internists and leaders in clinical research in their respective areas and include Hanna Bloomfield, MD, MPH; Tim Wilt, MD, MPH; Kris Ensrud, MD, MPH; Anne Joseph, MD, MPH; and Frank Lederle, MD.

The mentoring portion of the program is highly structured with meetings scheduled every two weeks during the mentor phase and monthly during the school phase. Dr. Lederle meets with the scholars on a monthly basis and research conferences are held every two weeks, affording the participants an opportunity to present their work. During the mentoring phase of the program, Dr. Timothy Wilt, CCDOR investigator and Director of the Cochrane Prostate Diseases and Urologic Cancers Review Group, will offer a course in systematic review. Clinical Scholars without a Masters degree will obtain an MPH or MS in Clinical Research from the University of MN School of Public Health.

Clinical Scholars will also be paired with one of three Scientific Mentors, statisticians who will guide scholars through the methodological aspects of their projects. Scientific Mentors include Thomas Rector, PharmD, PhD; David Nelson, PhD; and Siamek Noorbaloochi, PhD. Further, Dr. Rector's expertise will be made available to any MVAMC staff member doing research, including all faculty, investigators and fellows. Making such resources available to a wide group of VA staff is part of CCDOR's ongoing commitment to support research endeavors, thus strengthening ties with other sections of the medical center.

Presently, five Clinical Scholars are enrolled in the program:

Selcuk Adabag, MD, has been a cardiologist at the VA Medical Center since July 2000. His research interests include hypertrophic cardiomyopathy, heart failure and cardiac biomarkers.

Areef Ishani, MD, MS, has been a staff nephrologist at the VA Medical Center since 2002 and has been a CCDOR affiliate investigator since 2004. His research interests include chronic disease, diabetes mellitus, hypertension and nephrology.

Rebecca Rossom, MD, completed a U of M/VAMC sponsored Geriatric Psychiatry fellowship prior to joining the VAMC faculty in 2003. Her research interests include dementia, with a particular emphasis on behavioral difficulties, psychotic symptoms, and caregiving stresses associated with Alzheimer's dementia.

Mandeep Sawhney, MB, BS, has been a staff gastroenterologist at the VA Medical Center since 2001. His research interests include colon cancer screening and surveillance, endoscopic ultrasonography, and pancreas and biliary endoscopy.

Jasvinder Singh, MB, BS, MPH, has been a rheumatologist at the VA Medical Center since 2001. His research interests include systematic review, quality of care and quality of life in patients with rheumatic diseases, health status measures for gout, and botox treatment for relief of refractory joint pain.

CONGRATULATIONS

Thomas Rector, PhamD, PhD, was named a 2004 exceptional reviewer for *Medical Care*. Tom was one of only 15 reviewers nationally recognized for this honor.

Anne Joseph, MD, MPH, was promoted to Professor of Medicine in the University of Minnesota's Department of Medicine.

Greta Friedemann-Sánchez, PhD, submitted her book titled "Assembling Flowers and Cultivating Homes: Labor and Gender in Colombia" for publication.

Maureen Murdoch, MD, MPH and **Melissa Partin, PhD,** have been officially appointed to the VA Scientific Merit and Review Board (SMRB). They will serve on the board for a 3-year term.

Frank Lederle, MD, received the University of Minnesota Department of Medicine 2004 Faculty Award for Outstanding Research Contribution

Laura Kochevar, PhD, was appointed Director of the CRC-QUERI at the Minneapolis VAMC.

Drs. Melissa Partin, Dave Nelson, Diana Burgess, Laura Kochevar, Joan Griffin, Nina Sayer, and Yvonne Jonk received appointments as assistant professors in the University of Minnesota Department of Medicine.

FROM THE DIRECTOR

HANNA E. BLOOMFIELD, MD, MPH

It has been another strong year for CCDOR. We are extremely pleased that core investigator Dr. Frank Lederle was awarded a Center of Excellence in Clinical Research in October 2004. This Center for Epidemiological and Clinical Research (CECR), funded by VA OR&D, is one of only two Centers to be approved out of a field of 20 full proposals. CECR's goal is to increase clinical research capacity in the VA through a program of junior faculty development, to include formal training, mentoring, and access to research support. CECR will be nested within CCDOR enabling both Centers to leverage resources and increase efficiency. The funding of CECR is an important milestone in our strategic goal of strengthening the link between clinical and health services research.

Other recent funding highlights include:

Funding by NIH (NIDDK) of Dr. Wilt's R01 proposal to conduct systematic reviews in benign urological diseases. Specific areas of interest are assessing the effectiveness and cost-effectiveness of treatment interventions for common benign urological conditions including erectile dysfunction, benign prostatic hyperplasia, urinary incontinence and nephrolithiasis.

Dr. Partin received funding from VA HSR&D to assepatient-barriers to colorectal cancer screening in order to inform future patient-directed colorectal cancer screening promotion interventions.

Dr. Murdoch obtained VA HSR&D funding (along with Co-PI, Dr. Polusny) to assess what appears to be an exceptionally high rate of in-service sexual assault among Gulf War era male veterans who apply for PTSD disability benefits. This study will also assess the effectiveness and efficacy of current VA screening practices for military sexual trauma.

Dr. Fu successfully competed for a New Tobacco Investigator Award from the Minnesota Partnership for Action Against Tobacco. This study will combine qualitative and quantitative methods to examine ethnic differences in tobacco cessation outcomes and the relation of cultural factors to the use of tobacco treatment among racial/ethnic minority smokers.

I also would like to congratulate Dr. Gary Rosenthal and other VISN 23 colleagues in Iowa City who successfully competed for a new VA HSR&D Center of Excellence. We look forward to collaborating with them and other VA HSR&D colleagues throughout the country in future years.

QUERI CORNER

The Colorectal Cancer Quality Enhancement Research Initiative (CRC QUERI) mission is to promote the translation of research discoveries and innovations into patient care and systems improvements in order to reduce the incidence, late detection, suffering, and mortality from colorectal cancers among all veterans.

FY 2004 has been a momentous year for CRC QUERI. Melissa Partin's Veterans' Survey has been funded. Joan Griffin's Health Literacy study (VALUE) is completing its data collection. Joan and Greta Friedmann-Sánchez conducted local focus groups with veterans. Together, these projects lay the groundwork for future educational and motivational interventions to improve CRC screening. Diana Burgess and Laura Kochevar have been overseeing a study of primary care and GI providers and staff to get their impressions of what is needed to improve CRC screening and diagnosis. The Data System Group has done a terrific job of pulling together data from Austin, VistA, and Medicare for our Colorectal Cancer Screening and Follow-up Event data system (CRC-SAFE).

Special kudos to data manager and project coordinator Tammy Schult and to the MUMPS programming skills of Sean Nugent and the overall support from Sue Aumer and Dave Nelson.

In addition to these activities spearheaded by CCDOR partners, the QUERI is continuing partnerships with researchers across the country. The list of active research affiliates could go on for pages, but here are some of the partners who have new projects this year:

Deborah Fisher, MD, also from Durham, is investigating diagnostic delay and the validity of self reports of CRC screening.

Tom Imperiale, MD, (Indianapolis) has submitted a proposal to design an informatics system to recommend the best colonoscopy prep for each patient.

John Inandomi, MD, (Ann Arbor) is studying the effect of patient adherence on the cost effectiveness of CRC screening.

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